PATENT COOPERATION TREATY

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| ASTRAZENECA Global Intellectual Prope SE-151 85 Sodertalje | CODE | DATE | NTD | | CATION OF TRANSMITTAL OF TERNATIONAL PRELIMINARY |
| SUEDE | | | | | PORT ON PATENTABILITY |
| • | | <u> </u> | |] . | (PCT Rule 71.1) |
| | ANKOM 2 | 9 MAR 20 | 005 GP | Date of mailing | · · · · · · · · · · · · · · · · · · · |
| | DATA | | | (day/month/year) | 24.03.2005 |
| Applicant's or agent's file refer | DATA re-ENTERET | | | | |
| Applicant's or agent's file refer | DATA | | | | 24.03.2005 PORTANT NOTIFICATION |

- The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary report on patentability and its annexes, if any, established on the international application.
- A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
- 3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and malling address of the international preliminary examining authority:



European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465 **Authorized Officer**

Mazzariol, F

Tel. +49 89 2399-7911



PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

| Applicants or agents file reference | FOR FURTHER ACT | ION | See | Form PCT/IP | EA416 | |
|--|---|-----------------|--|-------------------|--|--|
| International application No. | International filing date (da | y/month/year) | Pı | nority date (da | ay/month/year) | |
| RCT/GB2004/001775 | 26.04.2004 | CODE | DATE 2 | .0 4\pq9 3 | | |
| | PC) or national classification and IPC | ANKOM 2 | MAD 20 | OF OUR | | |
| | | 2 | MAN ZU | US GIPS | | |
| Applicant ASTRAZENECA AB et al. | | DATA ENTERED | | | | |
| FINAL | | | | | | |
| Authority under Article 35 | This report is the international preliminary examination report is the international Freliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36. | | | | | |
| 2. This REPORT consists of | a total of 5 sheets, including this | cover sheet. | ٠. | | | |
| | anied by ANNEXES, comprising: | | | | | |
| to the state of th | nt and to the International Bureau) | | - | | • | |
| sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). | | | | | | |
| sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the | | | | | | |
| Supplemental I | • | | l manahan af | -l | | |
| sequence listing an | b. (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)), containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions). | | | | | |
| | | • | | | | |
| 4. This report contains indica | tions relating to the following item | ıs: | The state of the s | <u>=</u> | | |
| Box No. I Basis of | the opinion | | • | | • | |
| ☐ Box No. II Priority | | | | | | |
| ☐ Box No. III Non-esta | Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability | | | | | |
| Box No. IV Lack of unity of invention | | | | | | |
| Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement | | | | | | |
| | — | | | | - | |
| ☐ Box No. VII Certain d | lefects in the international applica | ition | • | | | |
| ☐ Box No. VIII Certain observations on the international application | | | | | | |
| Date of submission of the demand | | ate of complet | ion of this rep | port | | |
| | | | | | | |
| 29.10.2004 | . 2 | 4.03.2005 | | | | |
| Name and mailing address of the interpretiminary examining authority: | ernational A | uthorized Offic | er | | - Manager Mana | |
| European Patent Offic | _e | elephone No. | +49 89 2399- | | | |
| D-80298 Munich Tel. +49 89 2399 - 0 T Fax: +49 89 2399 - 44 | x: 523656 eomu d | | | | | |

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No. PCT/GB2004/001775

| | Box No. I Basis of the report | <u>t</u> | |
|-----------|--|--|--|
| • | With regard to the language , th filed, unless otherwise indicated | is report is based on the international appli I under this item. | cation in the language in which it was |
| | which is the language of a t international search (und publication of the internation | nslations from the original language into the translation furnished for the purposes of: der Rules 12.3 and 23.1(b)) ational application (under Rule 12.4) examination (under Rules 55.2 and/or 55.3 | |
| 2. | . With regard to the elements* of have been furnished to the rece report as "originally filed" and ar | the international application, this report is viving Office in response to an invitation und re not annexed to this report): | based on (replacement sheets which der Article 14 are referred to in this |
| | Paradottas Paras | | |
| | Description, Pages 1-8 | as originally filed | |
| | Claims, Numbers | | |
| | 1-13 | as originally filed | |
| | Drawings, Sheets | as originally filed | |
| | ☐ a sequence listing and/or ar | ny related table(s) - see Supplemental Box | Relating to Sequence Listing |
| 3. | ☐ The amendments have rest ☐ the description, pages ☐ the claims, Nos. ☐ the drawings, sheets/figs ☐ the sequence listing (specific any table(s) related to se | s ecify): | |
|). | ☐ This report has been estable had not been made, since they lead the description, pages ☐ the claims, Nos. | ished as if (some of) the amendments ann have been considered to go beyond the di)). | nexed to this report and listed below sclosure as filed, as indicated in the |
| | ☐ the drawings, sheets/ligs☐ the sequence listing (spe☐ any table(s) related to se | ecify): equence listing (specify): | |
| | + Tf item 4 applies co | ome or all of these sheets may l | ho marked "curerceded " |

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No. PCT/GB2004/001775

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| Novelty (N) | Yes: Claims No: Claims | 1-13 |
|-------------------------------|---------------------------|------|
| inventive step (IS) | Yes: Claims No: Claims | 1-13 |
| Industrial applicability (IA) | Yes: Claims | 1-13 |

2. Citations and explanations (Rule 70.7):

see separate sheet

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (SEPARATE SHEET)

PCT/GB2004/001775

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

D1: EP-A-1 188 808 (DAIKIN IND LTD) 20 March 2002 (2002-03-20) D2: DE 197 35 277 A (DEGUSSA) 18 February 1999 (1999-02-18)

2. The present application does not meet the requirement of Article 33(2) PCT for the following reasons:

D1-D2 disclose the use of polymer coated reactors for the manufacture of chemical or pharmaceutical compositions, the coating having non-sticking properties (see D1-D2: International Search Report). Although D2 does not explicitly discloses any pharmaceutical composition, this document is considered to disclose implicitly such compositions since it discloses in general chemical compounds which may be used as pharmaceutical compositions. Furthermore the problem addressed by D2 (reducing adhesion) is the same than the problem addressed by the present application; the solution being also the same (use of polymer coatings). Therefore the subject-matter of claims 1, 10 and 13 is not novel.

- 3. The technical features of claims 2-9, 11 and 12 are either known from D1-D2 or are considered to be merely one of several possibilities which the skilled person would select, in accordance with the circumstances, without the exercise of inventive skill. Consequently these claims do not meet the requirement of Article 33(3) PCT.
- 4. It is not at present apparent which part of the application could serve as a basis for a new, allowable claim. Should the applicant nevertheless regard some particular matter as meeting the requirements of Article 33(2)-(3) PCT an independent claim including such matter should be filed taking account of Rule 6.3 PCT.

The applicant should also indicate in the letter of reply any difference in term of concrete technical feature between the to-be-claimed subject-matter and the prior art and explain the significance thereof in term of inventive step, using the

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (SEPARATE SHEET)

International application No.

PCT/GB2004/001775

problem-solution approach. In particular he should explain which technical problem is solved by the claimed subject-matter and/or which surprising effect or advantage is obtained therewith in view of D1-D2.

Additional observations

- Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in D1 and D2 is not mentioned in the description, nor is this document identified therein.
- 2. In order to facilitate the examination of the conformity of the amended application with the requirements of Article 34(2)(b) PCT, the applicant is requested to clearly identify the amendments carried out, no matter whether they concern amendments by addition, replacement or deletion, and to indicate the passages of the application as filed on which these amendments are based (see also Rule 66.8(a) PCT). If the applicant regards it as appropriate these indications could be submitted in handwritten form on a copy of the relevant parts of the application as filed.
- The attention of the applicant is further drawn to the fact that the description should be in conformity with any amended claim as required by Rule 5.1(a)(iii) PCT.